



1 Having considered the parties' briefs and heard oral argument, and for the reasons stated below,  
2 the court will grant defendants' motion to dismiss.

### 3 BACKGROUND

#### 4 A. Plaintiff Michael Martin

5 According to his second amended complaint, plaintiff was diagnosed with Lumbar  
6 Spondylosis and Lumbar Degenerative Disc Disease in 2004. (Doc. No. 51 ¶ 13.) On February  
7 4, 2008, plaintiff was implanted with a Medtronic SynchroMed II implantable infusion system  
8 ("SynchroMed II"), consisting of a pump (model no. 8637-20, serial no. NGP315748H) and a  
9 catheter (model no. 8709SC, serial no. N132467011). (*Id.* ¶ 14.) In November 2008, during a  
10 trip to Arizona, plaintiff became seriously ill and was bedridden for two weeks. (*Id.* ¶ 15.) He  
11 sought medical attention when he returned home. (*Id.*) For the next five years, plaintiff  
12 underwent extensive diagnostic testing to determine the source of his illness; the testing left  
13 plaintiff with blurred vision, inability to walk, abdominal pain, and severe nausea, for four to five  
14 days a week. (*Id.* ¶ 16.) During this time, plaintiff experienced symptoms consistent with severe  
15 withdrawal-overdose cycles involving his opioid medication. (*Id.* ¶ 17.) Plaintiff alleges that  
16 defendants were aware that these symptoms were caused by his defective SynchroMed II device,  
17 even as plaintiff's medical providers were unable to determine the cause. (*See id.* ¶¶ 17–18.)

18 On July 12, 2013, after Medtronic agreed to allow for a pump replacement, plaintiff  
19 underwent a surgical procedure whereby his original SynchroMed II device was removed and  
20 replaced with a new SynchroMed II device (pump model no. 8637-20, serial no. NGP385091H;  
21 catheter model no. 8578). (*Id.* ¶¶ 19–20, 23.) During the procedure, the operating doctor  
22 discovered disintegration of material connecting the original pump and the catheter, as well as  
23 broken pieces and leakage of fluids around the pump-catheter connection site. (*Id.* at ¶ 21.)  
24 Plaintiff's medical records indicate that such leakage caused plaintiff's medication to flow  
25 directly into a pocket where the pump is located. (*Id.*) Plaintiff alleges he experienced pump-  
26 induced cycles of overdose and withdrawal: a temporary build-up of medication in the pocket  
27 caused overdose symptoms, followed by withdrawal symptoms as the pump emptied. (*Id.* at

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1 ¶ 25.) Plaintiff alleges he suffered physical and emotional injury, including lost time with his  
2 children. (*See id.* ¶ 26.)

3 **B. Regulatory and Legal Action Involving the SynchroMed II Device**

4 Plaintiff's claims against the Medtronic defendants are largely based on defendants'  
5 alleged "pattern of delayed responses to known safety violations" and disregard toward the  
6 "FDA's repeated warnings to comply with mandated manufacturing requirements." (*See id.* ¶ 1.)  
7 As alleged in plaintiff's second amended complaint, the SynchroMed II device is a Class III  
8 medical device, first approved through a pre-market approval ("PMA") process in 1988, by the  
9 U.S. Food and Drug Administration ("FDA"). (*Id.* ¶ 27.) In 2006, 2007, 2009, and 2012, the  
10 FDA issued warning letters concerning the manufacture of SynchroMed II devices and potential  
11 violations of federal regulations. (*See id.* ¶¶ 32, 34, 36, 40, Exs. 1, 3, 4, 6.)

12 In April 2013, the FDA determined that starting in September 2012, certain Medtronic  
13 catheters failed to comply with the approved specification, which allowed unintended  
14 disconnection of the catheter from the pump, failure of the catheter connector, leakage, or  
15 occlusion. (*See id.* ¶ 39, Ex. 5.) On June 3, 2013, a Class I recall was issued for certain  
16 SynchroMed II Sutureless Connector Intrathecal Catheters (model nos. 8709SC and 8731SC), and  
17 Sutureless Revision Kits (model nos. 8596SC and 8578), with a "use by" date prior to August 25,  
18 2014. (*Id.* ¶ 45, *see also id.*, Ex. 7.)

19 In 2015, the federal government filed a complaint against Medtronic for repeatedly failing  
20 to correct violations related to SynchroMed II devices. (*See id.* ¶¶ 49–54.) On April 27, 2015, a  
21 consent decree was approved in the U.S. District Court for the District of Minnesota enjoining  
22 Medtronic from further manufacture and distribution of certain defective SynchroMed II devices.  
23 (*Id.* ¶ 55.)

24 **LEGAL STANDARD**

25 The purpose of a motion to dismiss pursuant to Rule 12(b)(6) is to test the legal  
26 sufficiency of the complaint. *N. Star Int'l v. Ariz. Corp. Comm'n*, 720 F.2d 578, 581 (9th Cir.  
27 1983). "Dismissal can be based on the lack of a cognizable legal theory or the absence of  
28 sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't*, 901

1 F.2d 696, 699 (9th Cir. 1990). A claim for relief must contain “a short and plain statement of the  
2 claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). Though Rule 8(a)  
3 does not require detailed factual allegations, a plaintiff is required to allege “enough facts to state  
4 a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570  
5 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009). “A claim has facial plausibility when the  
6 pleaded factual content allows the court to draw the reasonable inference that the defendant is  
7 liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678.

8 In determining whether a complaint states a claim on which relief may be granted, the  
9 court accepts as true the allegations in the complaint and construes the allegations in the light  
10 most favorable to the plaintiff. *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984); *Novak v.*  
11 *United States*, 795 F.3d 1012, 1017 (9th Cir. 2015). It is inappropriate to assume that the plaintiff  
12 “can prove facts that it has not alleged or that the defendants have violated the . . . laws in ways  
13 that have not been alleged.” *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of*  
14 *Carpenters*, 459 U.S. 519, 526 (1983).

## 15 DISCUSSION

16 The Medtronic defendants move to dismiss plaintiff’s second amended complaint on  
17 grounds that each of plaintiff’s state law claims is preempted by the Medical Device Amendment  
18 (“MDA”) to the federal Food, Drug, and Cosmetic Act (“FDCA”). Defendants also contend that  
19 plaintiff’s second amended complaint fails to adequately allege facts to support plausible claims  
20 for relief, even if such claims are not preempted. The court addresses each of these arguments in  
21 turn below.

### 22 A. Federal Preemption

23 Under the Supremacy Clause, Congress has the power to preempt state law. U.S. Const.  
24 art. VI, cl. 2. Preemption may be express or implied. *Shaw v. Delta Airlines*, 463 U.S. 85, 97  
25 (1983) (citations omitted); *Montalvo v. Spirit Airlines*, 508 F.3d 464, 470 (9th Cir. 2007).

26 Express preemption occurs if a federal statute explicitly indicates that federal law is to  
27 supersede state law. *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993) (observing that  
28 “the task of statutory construction must in the first instance focus on the plain wording of the

1 clause, which necessarily contains the best evidence of Congress’ preemptive intent”); *Chicanos*  
2 *Por La Causa, Inc. v. Napolitano*, 558 F.3d 856, 863 (9th Cir. 2008). As the court previously  
3 noted, the MDA and its implementing regulations contain provisions expressly preempting  
4 certain state or local requirements that are “different from, or in addition to,” an existing FDA  
5 requirement relating to a particular medical device. *See* 21 U.S.C. § 360k(a); 21 C.F.R.  
6 § 808.1(d). (*See also* Doc. No. 50 at 7–9 (explaining the MDA’s regulatory regime).) For a state  
7 cause of action to be expressly preempted under the MDA, two conditions must be met. First, the  
8 FDA must have established specific requirements relating to a particular medical device at issue.  
9 *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996) (noting that state law will be preempted  
10 “only to the extent that the FDA has promulgated a federal ‘requirement’”); *Perez v. Nidek Co.,*  
11 *Ltd.*, 711 F.3d 1109, 1117 (9th Cir. 2013). The PMA process under the MDA imposes such a  
12 device-specific requirement. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322–23 (2008). Second,  
13 the state law claim must rely on a requirement that is “different from, or in addition to,” the  
14 FDA’s requirement, and must relate to the device’s safety or effectiveness. *See id.* at 323; *Lohr*,  
15 518 U.S. at 500; *Perez*, 711 F.3d at 1117; *see also Papike v. Tambrands Inc.*, 107 F.3d 737, 741  
16 (9th Cir. 1997) (holding that state common law claims can also impose “requirements” for  
17 preemption purposes). Conversely, the MDA does not preempt a “parallel” state law claim  
18 premised on a violation of FDA regulations. *See Riegel*, 552 U.S. at 330; *Stengel v. Medtronic*  
19 *Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013). Allegations that a defendant failed to comply with the  
20 FDA’s Current Good Manufacturing Practices (“CGMPs”) may support a parallel state law claim,  
21 but such noncompliance must be tied to the particular device at issue. *See, e.g., Frere v.*  
22 *Medtronic, Inc.*, No. EDCV 15-02338-BRO (DTBx), 2016 WL 1533524, at \*7 (C.D. Cal. Apr. 6,  
23 2016) (finding that while “alleged violations of CGMPs alone may be insufficient to establish a  
24 parallel claim,” plaintiff’s claim was not expressly preempted where she cited the FDA’s  
25 investigation of defendants’ CGMP violations and alleged her device was manufactured during a  
26 time defendants were cited for failure to comply with CGMPs).

27 Implied preemption, by contrast, occurs if congressional intent to preempt is “implicitly  
28 contained in [the] structure and purpose” of a federal law. *Montalvo*, 508 F.3d at 470 (quoting

1 *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992)). The MDA impliedly preempts claims  
2 that are based solely on violations of federal requirements, and not on state law requirements that  
3 could exist independently of any federal rules. *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S.  
4 341, 352–53 (2001); *Perez*, 711 F.3d at 1119; *cf. Lohr*, 518 U.S. at 500–502 (finding no  
5 preemption of plaintiff's state law claims because they arose from the manufacturer's alleged  
6 failure to use reasonable care in the production of the product, not solely from the violation of  
7 FDCA requirements); *Stengel*, 704 F.3d at 1230–33 (finding that a state law negligence claim  
8 escaped implied preemption because it could exist separately from any federal requirement to  
9 report adverse events to the FDA). Implied preemption under the MDA is rooted in the intent of  
10 Congress to vest exclusive authority over enforcement of the FDCA's provisions in the federal  
11 government. *See* 21 U.S.C. § 337(a); *accord Buckman*, 531 U.S. at 352; *Perez*, 711 F.3d at 1119.

12 At bottom, there is a “narrow gap” through which a plaintiff's state law claim must fit in  
13 order to escape preemption by the FDCA: “The plaintiff must be suing for conduct that *violates*  
14 the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be  
15 suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under  
16 *Buckman*).” *Perez*, 711 F.3d at 1120 (emphases in original) (quoting *In re Medtronic, Inc., Sprint*  
17 *Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). In his second amended  
18 complaint, plaintiff has attempted to thread this narrow gap while still alleging facts sufficient to  
19 state a plausible claim for relief.

20 1. Manufacturing Defect Claims

21 Plaintiff first alleges, in both strict liability and negligence causes of action, that his  
22 original SynchroMed II device suffered from a manufacturing defect. The MDA established a  
23 PMA process, which imposes comprehensive safety requirements applicable to Class III medical  
24 devices such as the SynchroMed II device at issue in this case. *See Riegel*, 552 U.S. at 322.  
25 California law, meanwhile, imposes general duties of care on medical device manufacturers in  
26 manufacturing their products. *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1110 (1996). “A  
27 manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to  
28 be used without inspection for defects, proves to have a defect that causes injury to a human

1 being.” *Id.* (quoting *Greenman v. Yuba Power Prods., Inc.*, 59 Cal. 2d 57, 62 (1963)). In  
2 addition, manufacturers are subject to liability for the manufacture of defective products under  
3 general principles of negligence. *See Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d  
4 987, 999–1000 (1991).

5 Here, plaintiff alleges that defendants’ failure to properly manufacture SynchronMed II  
6 devices in accordance with federal requirements also constituted a violation of California law.  
7 (*See* Doc. No. 51 ¶¶ 61–62.) As this court previously concluded, plaintiff’s claims are not subject  
8 to express preemption to the extent they are based on violations of federal requirements resulting  
9 from the PMA process. (*See* Doc. No. 50 at 11.) Plaintiff’s second amended complaint now also  
10 alleges facts from which it could be inferred that the SynchronMed II device was implanted in  
11 plaintiff during a time when defendants were not in compliance with CGMPs. (*See* Doc. No. 51  
12 ¶¶ 32–42.) Specifically, the FDA warned Medtronic in 2006 and 2007 that it may be  
13 manufacturing adulterated or misbranded products in breach of the FDCA as a result of these  
14 alleged violations. (*See id.* ¶¶ 32–35, Exs. 1, 3.) Thus, plaintiff’s manufacturing defect claims as  
15 alleged in his second amended complaint, which are based on violations of federal requirements,  
16 are not expressly preempted by the MDA. *See, e.g., Frere*, 2016 WL 1533524, at \*7; *De La Paz*  
17 *v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1094 (N.D. Cal. 2016) (“The Form 483s offer  
18 plausible support for the inference that [defendant] produced some adulterated devices, even if  
19 not conclusive.”).

20 The court also declines to conclude that either of plaintiff’s manufacturing defect claims  
21 as alleged in the second amended complaint is impliedly preempted by the MDA. While  
22 plaintiff’s claims rely on Medtronic’s alleged failures to comply with federal CGMPs, he now  
23 alleges that such instances of noncompliance independently constitute breaches of Medtronic’s  
24 duties under California’s strict liability and negligence laws. (*See* Doc. No. 51 ¶¶ 61, 90.)

25 Accordingly, the court concludes plaintiff’s manufacturing defect claims, brought by way  
26 of both strict liability and negligence causes of action in his second amended complaint, are not  
27 preempted by the FDA’s regulations relating to SynchronMed II devices.

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1           2.       Failure to Warn Claim

2           Plaintiff’s second amended complaint also alleges a strict liability cause of action based  
3 on a failure to warn of the dangers associated with plaintiff’s original SynchroMed II device. The  
4 MDA requires medical device manufacturers seeking PMA to disclose certain safety risks to the  
5 FDA, and imposes a continuing duty on PMA holders to report individual adverse events  
6 associated with those medical devices. *See* 21 U.S.C. § 360i(a); 21 C.F.R. § 803.10(c); *see also*  
7 *Stengel*, 704 F.3d at 1226–27 (explaining the PMA process and observing that, after approval,  
8 manufacturers are required to report adverse events to the FDA). California law imposes a  
9 general duty of reasonable care on manufacturers, and provides a strict products liability cause of  
10 action for failure to warn. *See Johnson v. Am. Standard, Inc.*, 43 Cal. 4th 56, 64–65 (2008); *Hufft*  
11 *v. Horowitz*, 4 Cal. App. 4th 8, 13 (1992) (“A manufacturer is strictly liable for injuries caused by  
12 a product that is . . . distributed without adequate instructions or warnings of its potential for  
13 harm.”). A failure to warn claim brought under state law will not be expressly preempted by the  
14 FDA so long as it “demand[s] the same conduct of manufacturers that federal law [does].” *Frere*,  
15 2016 WL 1533524, at \*5; *see also Stengel*, 704 F.3d at 1233 (holding that a state law negligence  
16 claim based on failure to warn was not expressly preempted because the “state-law duty  
17 parallel[ed the] federal-law duty” to report events to the FDA).

18           Here, plaintiff’s second amended complaint clarifies that its failure to warn claim is  
19 premised on defendants’ failure to report adverse events associated with the SynchroMed II  
20 device to the FDA, in accordance with requirements under the MDA—rather than a failure to  
21 report such events directly to medical providers and consumers. (*See* Doc. No. 51 ¶¶ 75–77, 82.)  
22 Accordingly, the court now concludes that this claim as alleged in plaintiff’s second amended  
23 complaint is not preempted under the MDA.

24           3.       Breach of Express Warranty Claim

25           Finally, plaintiff alleges a breach of express warranty claim. State law claims based on  
26 breach of express warranty can survive preemption under the MDA only to the extent that they  
27 seek to impose liability for misleading warranties voluntarily made outside the label. *See De La*  
28 *Paz*, 159 F. Supp. 3d at 1097–98 (“[T]he only claims for breach of the express warranty that have



1 survived preemption are those that went ‘beyond’ statements approved by the FDA.”); *Houston v.*  
2 *Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1181 (C.D. Cal. 2013) (noting that such claims are not  
3 preempted because where a defendant voluntarily makes misleading warranties outside the label,  
4 a plaintiff “is not imposing any requirement different from or additional to what federal law  
5 already requires”).

6 Here, plaintiff alleges only that defendants expressly warranted that the pump and catheter  
7 in plaintiff’s SynchroMed II device were safe and fit for use. (Doc. No. 51 ¶¶ 112–13.) Just as  
8 this court previously concluded, plaintiff’s state law claim for breach of express warranty, as pled  
9 in his second amended complaint, is expressly preempted under the MDA because it fails to  
10 plausibly allege that defendants breached any warranty made beyond FDA-approved statements.  
11 *See De La Paz*, 159 F. Supp. 3d at 1098 (“Any claim for breach of express warranty based on  
12 [FDA-approved] statements would require a determination that [defendant] did not conform to  
13 the descriptions approved by the FDA. Such claims are preempted.”). Moreover, plaintiff has  
14 failed to specifically allege whether defendants’ purported liability is based on a deviation from  
15 the FDA’s requirement, rather than misleading voluntary off-label warranties. As a result,  
16 plaintiff’s breach of express warranty claim is preempted under the MDA.

## 17 **B. Sufficiency of Pleadings**

18 To the extent the court has concluded that plaintiff’s claims are not preempted under  
19 federal law, however, the court also finds that plaintiff has failed to allege facts sufficient to  
20 support plausible claims for relief.

### 21 1. Manufacturing Defect & Failure to Warn Claims

22 Generally speaking, in order to state a parallel claim premised on a violation of FDA  
23 regulations, a plaintiff must allege (1) the violation of a specific federal requirement applicable to  
24 the device, and (2) a causal nexus between the violation and the alleged injury. *See, e.g., Wolicki-*  
25 *Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296, 1300–02 (11th Cir. 2011); *Eidson v. Medtronic, Inc.*,  
26 40 F. Supp. 3d 1202, 1215 (N.D. Cal. 2014); *Hawkins v. Medtronic, Inc.*, No. 1:13-cv-00499-  
27 AWI-SKO, 2014 WL 346622, at \*5 (E.D. Cal. Jan. 30, 2014); *Knoppel v. St. Jude Med., Inc.*, No.  
28 SACV 13-383 JVS (ANx), 2013 WL 12116393, at \*3 (C.D. Cal. Sept. 24, 2013). To state a

1 manufacturing defect claim by way of either a strict products liability or a negligence cause of  
2 action, a plaintiff must allege, and eventually prove, a particular manufacturing defect which  
3 caused injury to the plaintiff. *See County of Santa Clara v. Atl. Richfield Co.*, 137 Cal. App. 4th  
4 292, 318 (2006) (describing the elements of a strict products liability cause of action); *Marlene F.*  
5 *v. Affiliated Psychiatric Med. Clinic, Inc.*, 48 Cal. 3d 583, 588 (1989) (reciting the traditional  
6 elements of negligence). Likewise, “[t]o state a claim for strict products liability for failure to  
7 warn, a plaintiff must allege that the defendant failed to adequately warn of a known or knowable  
8 risk where that failure caused the plaintiff’s injuries.” *Hawkins*, 2014 WL 346622, at \*13 (citing  
9 *Carlin*, 13 Cal. 4th at 1112).

10 Plaintiff’s second amended complaint, however, fails to identify a particular  
11 manufacturing defect violative of the MDA that caused plaintiff’s injury. As he did in his first  
12 amended complaint, plaintiff again merely points to a series of regulatory and legal actions taken  
13 by the FDA between 2006 and 2015 (*see* Doc. No. 51 ¶¶ 32–56), involving noncompliance with  
14 the FDA’s CGMPs. But the allegations of the second amended complaint fail to link any of these  
15 actions or instances of noncompliance to plaintiff’s particular SynchroMed II device, originally  
16 implanted in plaintiff in 2008. For example, the FDA sent Medtronic warning letters in 2006 and  
17 2007, but neither of these letters references the models or components of plaintiff’s device that he  
18 alleges were defective. (*See id.* ¶¶ 32, 34, Exs. 1, 3.) The FDA also sent other warning letters in  
19 2009 and 2012, after plaintiff’s original device was implanted. (*See id.* ¶¶ 36, 40, Exs. 4, 6.)  
20 Those letters also fail to identify the specific models or components of plaintiff’s device.  
21 Furthermore, neither the June 2013 recall nor the April 2015 consent decree reference or pertain  
22 to the models or components linked to plaintiff’s original SynchroMed II device. (*See id.* ¶¶ 45,  
23 55, Ex. 7.) Instead, plaintiff appears to proceed on a generalized theory that documented  
24 noncompliance with respect to *certain* models of, or issues involving, the SynchroMed II device  
25 necessarily rendered *plaintiff’s* original device also defective. Simply put, the court cannot  
26 plausibly infer a link between these documented incidents and plaintiff’s original SynchroMed II  
27 device. Nor can it infer a causal connection between any alleged manufacturing defect and  
28 plaintiff’s injury. *See, e.g., De La Paz*, 159 F. Supp. 3d at 1095 (“[Plaintiff’s] failure to allege a

1 causal link between any adulteration of [defendants’] device and her injuries is fatal to her  
2 manufacturing-defect claims.”); *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) (finding  
3 “impermissibly conclusory and vague” allegations stating that “the [device] contained a  
4 manufacturing defect in that it was manufactured in such a manner that impurities, residues, and  
5 bacteria remained on the [device] in violation of the FDA standards and requirements and in  
6 violation of the manufacturing processes and design approved by the FDA”). Thus, while  
7 plaintiff’s manufacturing defect claims may not be preempted, they must be dismissed for failure  
8 to sufficiently state a claim.

9 Similarly, plaintiff’s failure to warn claim also lacks a sufficient factual basis from which  
10 to infer causation or liability. As noted above, plaintiff’s failure to warn claim escapes  
11 preemption only to the extent it is premised on Medtronic’s failure to report certain adverse  
12 events to the FDA. However, in his second amended complaint, plaintiff has not alleged facts  
13 identifying the nature of any such adverse events or addressing how any such failure to report  
14 ultimately caused plaintiff’s injury. Thus, the court cannot draw a plausible inference that in the  
15 absence of such a failure to report, the FDA would have alerted plaintiff’s doctors or plaintiff  
16 himself such that plaintiff would have refused implantation of his original SynchroMed II device.  
17 *See Hawkins*, 2014 WL 346622, at \*8 (“Plaintiff generally alleges that Defendants failed to report  
18 adverse events to the FDA. He also generally alleges that these failures caused or contributed to  
19 his injuries. What is not alleged is any factual content that would support the causal nexus.”).  
20 Because plaintiff fails to plead sufficient facts to support liability stemming from a failure to  
21 warn, this claim must also be dismissed.

## 22 2. Breach of Express Warranty Claim

23 As the court concluded above, plaintiff’s breach of express warranty claim is preempted  
24 under the MDA. Even assuming plaintiff’s claim were not to be preempted, his second amended  
25 complaint again falls far short of pleading facts sufficient to raise an inference of liability with  
26 respect to such a claim. To state a claim for relief for a breach of express warranty, plaintiff must  
27 allege that: (i) defendants made an “affirmation or promise” or provided a “description” of the  
28 device; (ii) the statement was “part of the basis of the bargain;” and (iii) defendants breached the

1 warranty. *Weinstat v. Dentsply Int'l, Inc.*, 180 Cal. App. 4th 1213, 1227 (2010) (citing Cal. Com.  
2 Code § 2313(1)). “[A]n affirmation merely of the value of the goods or a statement purporting to  
3 be merely the seller’s opinion or commendation of the goods does not create a warranty.” Cal.  
4 Com. Code § 2313(2). Plaintiff’s second amended complaint fails to allege the contents of any  
5 express warranty made by defendants. Moreover, it remains unclear from the allegations of the  
6 second amended complaint whether the alleged warranty contained affirmations of fact sufficient  
7 to form the basis of an express warranty claim, or whether they simply reflected opinions or  
8 commendations regarding plaintiff’s SynchroMed II device. Plaintiff also fails to plead any non-  
9 conclusory allegations as to how any warranties were made to him or his physician, and whether  
10 any alleged warranties were relied upon by either. *See Hammarlund v. C.R. Bard, Inc.*, 2:15-cv-  
11 05506-SVW-JEM, 2015 WL 5826780, at \*5 (C.D. Cal. Oct. 2, 2015). As a result, plaintiff’s  
12 express warranty claim must be dismissed, in the alternative, for failure to state a claim.

13 **C. Leave to Amend**

14 The undersigned has carefully considered whether plaintiff should be granted further leave  
15 to amend. “Valid reasons for denying leave to amend include undue delay, bad faith, prejudice,  
16 and futility.” *Cal. Architectural Bldg. Prods., Inc. v. Franciscan Ceramics, Inc.*, 818 F.2d 1466,  
17 1472 (9th Cir. 1988); *see also Klamath–Lake Pharm. Ass’n v. Klamath Med. Serv. Bureau*, 701  
18 F.2d 1276, 1293 (9th Cir. 1983) (holding that while leave to amend shall be freely given, the  
19 court need not allow futile amendments). Here, plaintiff has, in the court’s view, been unable to  
20 cure all of the deficiencies noted in the order dismissing his first amended complaint. At the  
21 hearing on this motion to dismiss, plaintiff’s counsel indicated that plaintiff had alleged all of the  
22 available facts in support of his claims and did not argue for the granting of further leave to  
23 amend. The court has concluded, as set forth above, that the allegations of the second amended  
24 complaint fail to state a plausible claim for relief. Accordingly, the undersigned concludes that  
25 the granting of further leave to amend would be futile.

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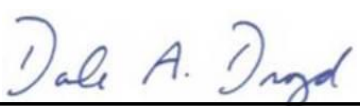
**CONCLUSION**

For the reasons set forth above,

1. Defendants’ motion to dismiss plaintiff’s second amended complaint (Doc. No. 55) is granted;
2. Plaintiff’s second amended complaint (Doc. No. 51) is dismissed with prejudice; and
3. The Clerk of the Court is directed to close this case.

IT IS SO ORDERED.

Dated: October 13, 2017

  
UNITED STATES DISTRICT JUDGE